III. REMARKS/ARGUMENTS

A. Status of the Application

Claims 2-13, 16-18 and 20 have been amended. Claims 1, 14, 15 and 19 have been cancelled without prejudice or disclaimer. New claims 22-24 have been added. Thus, claims 2-13, 16-18, and 20-24 are currently pending in this application.

The claim amendments made herein are not in response to rejections made in the present Office Action, but rather the claim amendments made herein are made to enhance the Applicants' patent portfolio with claims of varying scope, and/or are of a grammatical nature.

No new matter has been added by the amendments and new claims presented herein. Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

B. Rejection of Claims 3-4, 6-9 and 15-18 under 35 U.S.C. § 112

Claims 3-4, 6-9 and 15-18 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

Claims 3 and 4 have been amended to replace the recitation of the term "micelles" with the term "reverse micelles". Claims 3 and 4 have also been amended to delete the unnecessary reference to "in a fluid environment". Claims 3 and 4 have further been amended for consistency with the preamble of claim 2.

Claim 6 has been amended to replace the recitation of the term "amphipathic compound" with the term "amphipathic ionic compound". Claim 6 has also been amended for consistency with the preamble of claim 2.

Claim 7 has been amended to delete the unnecessary reference to "high solubility" and "low permeability", and for consistency with the preamble of claim 2. Applicant submits that recitation of a "Class III biopharmaceutical" in claim 7 is not indefinite because those of ordinary skill in the art would recognize and understand what is meant by the recitation. (*See e.g.,* Amidon, GL et al., *"A theoretical basis for a biopharmaceutic drug classification: the correlation of in vitro drug product dissolution and in vivo bioavailability",* Pharm Res. (3):413-20, 1995) (copy of abstract obtained at www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd =Retrieve&db=pubmed&dopt=Abstract&list_uids=7617530 is attached).

Claim 8 has been amended for consistency with the preamble of claim 2. With respect to the rejection under 35 U.S.C. § 112, second paragraph, Applicant notes that claim 2, from which claim 8 depends, sets forth a composition comprising an amphipathic ionic compound in monomeric form, and a polar ionizable agent of interest. Applicant submits that the antecedent basis established in claim 2 is sufficiently clear for the recitations in claim 8.

Claim 9 has been amended to replace the recitation of the term "amphipathic compound" with the term "amphipathic ionic compound". Claim 9 has also been amended for consistency with the preamble of claim 2 and for grammatical accuracy.

Claim 15 has been cancelled and rewritten as new claim 24 because marking the corrections to the punctuation of claim 15 may have been confusing. Further, recitation of "urinary" and "vaginal" has been deleted in new claim 24, and new claim 24 also recites language consistent with the preamble of claim 2.

Claim 16 has been amended to replace the term "matrix-type" with the term "matrix", and for consistency with the preamble of claim 2.

Claim 17 has been amended for consistency with the preamble of claim 2. Applicant notes that claim 2, from which claim 17 depends, sets forth a composition comprising an amphipathic ionic compound in monomeric form, and a polar ionizable agent of interest. Applicant submits that the subject matter of claim 2 is such that it can be manipulated in a solid state as recited in claim 17.

Claim 18 has been amended for consistency with the preamble of claim 2, and for proper Markush format. Applicant notes that claim 2, from which claim 18 depends, sets forth a composition comprising an amphipathic ionic compound in monomeric form, and a polar ionizable agent of interest. Applicant submits that the subject matter of claim 2 is such that it can be manipulated in a solid state as recited in claim 18.

In view of the foregoing, Applicant respectfully requests that the rejection of claims 3-4, 6-9, and 15-18 under 35 U.S.C. § 112, second paragraph be withdrawn.

C. Rejection of Claim 19 under 35 U.S.C. § 101

Claim 19 stands rejected under 35 U.S.C. § 101. This rejection has been rendered moot by the cancellation of claim 19.

D. Rejection of Claims 1-9, 13-15 and 18-21 under 35 U.S.C. 102(b)

Claims 1-9, 13-15 and 18-21 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,292,499 to Evans et al. (hereafter referred to as "Evans"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Evans must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(b). Claims 1, 14, 15 and 19 have been cancelled. As applied to the remaining claims however, Applicant notes that Evans does not meet the standard required by MPEP § 2131 because Evans does not disclose or suggest each and every element of independent claim 2 or the claims dependent thereon.

Claim 2 as amended is drawn to a pharmaceutical composition comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the pharmaceutical composition is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the pharmaceutical composition comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Evans discloses an aerosol formulation comprising water, a propellant, and reverse micelles of a hydrophilic pharmaceutically active agent. The aerosol formulation, which includes water and the reverse micelles, is delivered to a patient. (See e.g., Col. 6, lines 44-54.) While Evans discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Evans does not disclose or suggest a pharmaceutical composition comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Evans does not disclose or suggest a pharmaceutical composition wherein a reverse micelle comprising an amphipathic ionic compound and a polar ionizable agent of interest is formed after the pharmaceutical composition is contacted with an aqueous fluid.

Claims 3-9, 13, 18 and 20-21 each depend directly or indirectly from claim 2. Thus, the rejection of claims 3-9, 13-15, 18 and 20-21 based on Evans is also improper for at least the same reasons as applied to claim 2.

In view of the foregoing, Applicants request that the rejection of claims 1-9, 13-15 and 18-21 under 35 U.S.C. § 102(b) over Evans be withdrawn.

E. Rejection of Claims 1-6, 8-11, 13-15 and 18 under 35 U.S.C. § 102(b)

Claims 1-6, 8-11, 13-15 and 18 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,770,172 to Linehan et al. (hereafter referred to as "Linehan"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Linehan must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(b). Claims 1, 14 and 15 have been cancelled. As applied to the remaining claims however, Applicant notes that Linehan does not meet the standard required by MPEP § 2131 because Linehan does not disclose or suggest each and every element of independent claim 2 or the claims dependent thereon.

Claim 2 as amended is drawn to a pharmaceutical composition comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the pharmaceutical composition is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the pharmaceutical composition comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Linehan describes a process for producing a nanometer-sized metal compound. According to the process described in Linehan, a water-soluble metal compound is reacted in a reverse micelle to form a nanometer-sized metal compound. The nanometer-sized compound is precipitated from the reverse micelle. (Col. 5, lines 32-37). Linehan does not disclose or suggest a pharmaceutical composition comprising an amphipathic ionic compound in

monomeric form and a polar ionizable agent of interest. Further, Linehan does not disclose or suggest a pharmaceutical composition wherein a reverse micelle comprising an amphipathic ionic compound and a polar ionizable agent of interest is formed after the pharmaceutical composition is contacted with an aqueous fluid.

Claims 3-6, 8-11, 13 and 18 each depend directly or indirectly from claim 2. Thus, the rejection of claims 3-6, 8-11, 13 and 18 based on Linehan is also improper for at least the same reasons as applied to claim 2.

In view of the foregoing, Applicants request that the rejection of claims 1-6, 8-11, 13-15 and 18 under 35 U.S.C. § 102(b) over Linehan be withdrawn.

F. Rejection of Claims 1-2, 5-7, 12-14 and 16-21 under 35 U.S.C. § 102(a)

Claims 1-2, 5-7, 12-14 and 16-21 stand rejected under 35 U.S.C. § 102(a) over U.S. Patent No. 6,316,497 to Liu et al. (hereafter referred to as "Liu"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Liu must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(a). Claims 1, 14 and 19 have been cancelled. As applied to the remaining claims however, Applicant notes that Liu does not meet the standard required by MPEP § 2131 because Liu does not disclose or suggest each and every element of independent claim 2 or the claims dependent thereon.

Claim 2 as amended is drawn to a pharmaceutical composition comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the pharmaceutical composition is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the pharmaceutical composition comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Liu discloses a system comprising o-(chloroacetylcarbamoyl)fumigillol, a pharmaceutically acceptable carrier, and a stabilizing component, such as water, acid or a complex-forming agent. When water is the stabilizing component in the system, and surfactants are present, reverse micelles form. The formation of the reverse micelles protects the o-(chloro acetylcarbamoyl)fumigillol from degradation, or stabilizes the o-(chloroacetylcarbamoyl) fumigillol in the macroscopically homogeneous SES solution. (Col. 5, lines 24-37). Thus, Liu describes forming a system in which reverse micelles are formed prior to administration of a drug so that the drug remains intact for administration.

While Liu discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Liu does not disclose or suggest a pharmaceutical composition comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Liu does not disclose or suggest a pharmaceutical composition wherein a reverse micelle comprising an amphipathic ionic compound and an polar ionizable agent of interest is formed after the pharmaceutical composition is contacted with an aqueous fluid.

Claims 5-7, 12-13, 16-18 and 21 each depend directly or indirectly from claim 2. Thus, the rejection of claims 5-7, 12-13, 16-18 and 21 based on Liu is also improper for at least the same reasons as applied to claim 2.

In view of the foregoing, Applicants request that the rejection of claims 1-2, 5-7, 12-14 and 16-21 under 35 U.S.C. § 102(a) over Liu be withdrawn.

G. Rejection of Claims 1, 5-7, 9-10, 13-15 and 19-21 under 35 U.S.C. § 102(e)

Claims 1, 5-7, 9-10, 13-15 and 19-21 stand rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,429,200 to Monahan et al. (hereafter referred to as "Monahan"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Monahan must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(e). Claims 1, 14, 15 and 19 have been cancelled. The remaining rejected claims, namely, claims 5-7, 9-10, 13, 18 and 20-21, each depend directly or indirectly from claim 2. As applied to the remaining claims, Applicant notes that Monahan does not meet the standard required by MPEP § 2131 because Monahan does not disclose or suggest each and every element of independent claim 2 or the claims dependent thereon.

Claim 2 as amended is drawn to a pharmaceutical composition comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the pharmaceutical composition is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the pharmaceutical composition comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Monahan discloses a complex for administration to a patient, which is formed by inserting a nucleic acid into a reverse micelle. (Abstract). Thus, Monahan describes a complex in which reverse micelles are formed prior to administration of a drug. While Monahan discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Monahan does not disclose or suggest a pharmaceutical composition comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Monahan does not disclose or suggest a pharmaceutical composition wherein a reverse micelle comprising an amphipathic ionic compound and an polar ionizable agent of interest is formed after the pharmaceutical composition is contacted with an aqueous fluid.

Claims 5-7, 9-10, 13, and 20-21 each depend directly or indirectly from claim 2. Thus, the rejection of claims 5-7, 9-10, 13, and 20-21 based on Monahan is also improper for at least the same reasons as applied to claim 2.

In view of the foregoing, Applicants request that the rejection of claims 1, 5-7, 9-10, 13-15 and 19-21 under 35 U.S.C. § 102(a) over Monahan be withdrawn.

H. New Claims 22-24

New claim 22 has been added to specify that the one, or more than one ionic compound and the one, or more than one polar ionizable agent of interest are oppositely charged. Support for new claim 22 is provided throughout the specification, for example, at page 13, line 17 to page 14, line 4 of the description.

Claim 14, which is cancelled herein, has been rewritten as new claim 23 because marking the corrections to the punctuation of claim 14 may have been confusing. New claim 23 also recites language consistent with the preamble of claim 2.

Claim 15, which is cancelled herein, has been rewritten as new claim 24 because marking the corrections to the punctuation of claim 15 may have been confusing. Further, recitation of "urinary" and "vaginal" has been deleted in new claim 24, and new claim 24 also recites language consistent with the preamble of claim 2.

Each of new claims 22-24 depend directly or indirectly from claim 2. Thus, Applicant submits that claims 22-24 are allowable for at least the same reasons as claim 2.

H. Additional Amendments

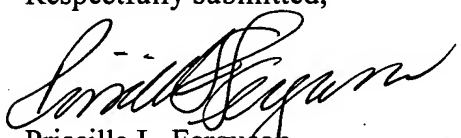
Amendments made to claims 5, 10, 11, 12, 13 and 20 not discussed above were made to provide consistency with the preamble of claim 2, and to correct one or more of punctuation, spelling and grammar in the claims.

IV. CONCLUSION

Claims 2-13, 16-18, and 20-24 are under consideration in the present application. In view of the foregoing remarks, allowance of claims 2-13, 16-18, and 20-24 is respectfully requested.

The examiner is invited to call the undersigned at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

Respectfully submitted,



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Priscilla L. Ferguson
Registration No. 42,531

HAYNES AND BOONE, LLP
901 Main Street, Suite 3100
Dallas, Texas 75212-3789
Telephone: 214/651-5662
IP Facsimile No. 214/200-0853
File: 25000.9
1286087_1.DOC